

### **AMENDMENTS TO THE CLAIMS**

Please amend the claims as follows. This listing of claims replaces and supersedes all previous versions:

1. (currently amended) A food intake-limiting device for peroral implantation in the stomach adjacent a gastroesophageal junction, comprising:
  - inner and outer elements defining an ingestion chamber with a proximal entry opening and a distal exit opening to limit a rate of efflux;
  - a plurality of openings in the outer element for protrusion of stomach lining to the inner element;
  - wherein the inner element includes a plurality of retention members to hold the protruding stomach lining, wherein the retention members comprise tangential spikes, whereby the device is secured to the stomach lining; and
  - wherein the inner and outer elements are frustoconically tapered from a relatively larger proximal radius to a relatively smaller distal radius.
2. (original) The device of claim 1 wherein the inner and outer elements comprise nested baskets.
3. (original) The device of claim 1 wherein the openings are formed by a mesh in the outer element.
4. (canceled)

5. (original) The device of claim 1 wherein the inner and outer elements are rotatable with respect to each other to actuate the retention members.
6. (original) The device of claim 1 wherein the retention members are releasable.
7. (original) The device of claim 1 comprising a distal end ring in the outer element, and a proximal end ring in the inner element.
8. (cancelled)
9. (currently amended) The device of claim 1 wherein the inner element comprises mesh openings and the ~~retention members comprise~~ spikes are tangentially oriented in a plurality of the mesh openings.
10. (previously presented) A food intake-limiting device for peroral implantation in the stomach adjacent a gastroesophageal junction, comprising:
  - an inner basket nested in an outer basket, further comprising a distal end ring in the outer basket and a proximal end ring in the inner basket;
  - a proximal entry opening and a distal exit opening to limit a rate of efflux;
  - a mesh structure in the outer basket;
  - a plurality of spikes mounted tangentially on the inner basket adjacent mesh openings in the outer basket, wherein the inner basket is rotatable with respect to the outer basket

between a release position comprising a gap between points of the spikes and mesh elements of the outer basket and a second position comprising an overlap between the points of the spikes and the mesh elements; and

wherein the inner and outer baskets are frustoconically tapered from a relatively larger proximal radius to a relatively smaller distal radius.

11. (cancelled)

12. (cancelled)

13. (previously presented) The device of claim 10 wherein the inner basket has mesh openings and the spikes are tangentially oriented in a plurality of the mesh openings.

14. (previously presented) A food intake-limiting device for peroral implantation in the stomach adjacent a gastroesophageal junction, comprising:

an inner element nested in an outer element, wherein the inner and outer elements are frustoconically tapered from a relatively larger proximal radius to a relatively smaller distal radius;

a proximal entry opening and a distal exit opening to limit a rate of efflux;

mesh openings in the outer element for protrusion of stomach lining into the outer element;

a plurality of spikes mounted tangentially on the inner element for transfixing the protruding stomach lining, wherein the inner element is rotatable with respect to the outer element to effect the transfixation.

15.(original) A tool for peroral manipulation of the device of claim 13 in the stomach adjacent the esophageal junction, comprising in combination therewith an inner tube slideably and rotatably received in an outer tube, a hub on a distal end of each of the inner and outer tubes for releasably engaging a respective end ring of the outer and inner baskets, a handle on a proximal end of each of the inner and outer tubes, and a connector for placing a vacuum or pressure source in fluid communication with perforations in the inner tube adjacent the distal end thereof.

16.(original) A method for peroral implantation of an intake-restricting device in a stomach of a patient adjacent a gastroesophageal junction using the tool of claim 15, comprising the steps of securing the distal hub of the inner tube in the end ring of the outer basket, securing the distal hub of the outer tube in the end ring of the inner basket, inserting the inner and outer baskets through the mouth and esophagus of the patient and positioning them below the esophageal junction, applying vacuum to the connector to draw stomach lining into the mesh openings of the outer basket, manipulating the proximal handles to rotate the inner basket with respect to the outer basket, transfix stomach lining protruding into the mesh openings and fix the baskets in place, terminating the vacuum application, disengaging the distal

hub of the inner tube from the end ring of the outer basket, disengaging the distal hub of the outer tube from the end ring of the inner basket, and withdrawing the tool.

17.(original) A method for peroral extraction of the intake-restricting device implanted in a stomach adjacent a gastroesophageal junction of a patient using the tool of claim 15, comprising the steps of inserting a distal end of the tool through the mouth and esophagus of the patient, securing the distal hub of the inner tube in the end ring of the outer basket, securing the distal hub of the outer tube in the end ring of the inner basket, manipulating the proximal handles to rotate the inner basket with respect to the outer basket and open a gap between each point of the spikes and the adjacent mesh member, applying pressure to the connector to disengage stomach lining from the spikes and the mesh openings of the outer basket, and removing the inner and outer baskets through the esophagus and mouth of the patient.

18.. (previously presented) The device of claim 10 comprising a distal end ring in the outer basket, and a proximal end ring in the inner basket.

19.(currently amended) A method for peroral implantation of an ~~the~~ intake-restricting device ~~of claim 5~~ in a stomach of a patient adjacent a gastroesophageal junction, wherein the intake-restricting device comprises inner and outer elements defining an ingestion chamber with a proximal entry opening and a distal exit opening to limit a rate of efflux, a plurality of openings in the outer element for protrusion of

stomach lining to the inner element, wherein the inner element includes a plurality of retention members to hold the protruding stomach lining, wherein the inner and outer elements are rotatable with respect to each other to actuate the retention members, whereby the device is secured to the stomach lining, and wherein the inner and outer elements are frustoconically tapered from a relatively larger proximal radius to a relatively smaller distal radius, comprising the steps of:

providing a manipulation tool, comprising:

- an inner tube slideably and rotatably received in an outer tube;

- a hub on a distal end of each of the inner and outer tubes for releasably engaging a respective distal end of the outer element and a proximal end of the inner element;

- a handle on a proximal end of each of the inner and outer tubes; and

- a connector for placing a vacuum source in fluid communication with perforations in the inner tube adjacent the distal end thereof;

securing the distal hub of the inner tube in the distal end of the outer element;

securing the distal hub of the outer tube in the proximal end of the inner element;

inserting the inner and outer elements through the mouth and esophagus of the patient and positioning them below the esophageal junction;

- applying vacuum to the connector to draw stomach lining into the plurality of openings in the outer element;
- manipulating the proximal handles to rotate the inner element with respect to the outer element to actuate the retention members to hold the stomach lining protruding into the plurality of openings and fix the inner and outer elements in place;
- terminating the vacuum application;
- disengaging the distal hub of the inner tube from the distal end of the outer element;
- disengaging the distal hub of the outer tube from the proximal end of the inner element; and
- withdrawing the tool.
20. (previously presented) The method of claim 19 wherein the retention elements comprise tangential spikes.
21. (previously presented) The method of claim 19 wherein the inner and outer elements comprise nested baskets and wherein the openings are formed by a mesh in the outer basket.
22. (previously presented) The method of claim 19 comprising a distal end ring in the outer element, and a proximal end ring in the inner element.
23. (currently amended) A method for peroral extraction of an ~~the~~ intake-restricting device ~~of claim 5~~ implanted in a stomach adjacent a gastroesophageal junction of a patient, wherein the intake-restricting

device comprises inner and outer elements defining an ingestion chamber with a proximal entry opening and a distal exit opening to limit a rate of efflux, a plurality of openings in the outer element for protrusion of stomach lining to the inner element, wherein the inner element includes a plurality of retention members to hold the protruding stomach lining, wherein the inner and outer elements are rotatable with respect to each other to actuate the retention members, whereby the device is secured to the stomach lining, and wherein the inner and outer elements are frustoconically tapered from a relatively larger proximal radius to a relatively smaller distal radius, comprising the steps of:

inserting a distal end of a manipulation tool through the mouth and esophagus of the patient, wherein the manipulation tool comprises:

- an inner tube slideably and rotatably received in an outer tube;
- a hub on a distal end of each of the inner and outer tubes for releasably engaging a respective distal end of the outer element and a proximal end of the inner element;
- a handle on a proximal end of each of the inner and outer tubes; and
- a connector for placing a pressure source in fluid communication with perforations in the inner tube adjacent the distal end thereof;

securing the distal hub of the inner tube in the distal end of the outer element;

securing the distal hub of the outer tube in the proximal end of the inner element;



manipulating the proximal handles to rotate the inner element with respect to the outer element to release the retention members; applying pressure to the connector to disengage stomach lining from the retention members and the plurality of openings in the outer element; and removing the inner and outer elements through the esophagus and mouth of the patient.